

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

*Patricia Lindberg, et al. v. Ethicon, Inc., et al.* Civil Action No. 2:12-cv-01637

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Konstantin Walmsley, M.D.)**

Pending before the court is the Motion to Exclude the Testimony of Konstantin Walmsley, M.D. [ECF No. 43] filed by the defendants. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file general causation *Daubert* motions in the main MDL and specific causation *Daubert* motions, responses, and replies in the individual member cases. To the extent that an expert is both a general and specific causation expert, the parties were advised that that they could file a general causation motion in the main MDL 2327 and a specific causation motion in an individual member case. PTO No. 217, at 4.

## **II. Legal Standard**

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that “a reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

*Id.* at 262 (citations omitted). “A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Id.* at 265. However, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* “The alternative causes suggested by a defendant ‘affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,’ unless the expert can offer ‘no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the

sole cause.” *Id.* at 265 (citations omitted).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

### III. Discussion

Ethicon first argues that I should exclude Dr. Walmsley’s opinion that the TVT Secur device caused Ms. Lindberg’s dyspareunia because it is irrelevant, speculative, and mere *ipse dixit*. However, after reviewing the record, I find that Dr. Walmsley’s opinions linking the TVT Secur device to Ms. Lindberg’s dyspareunia are relevant and sufficiently grounded to move forward. To the extent Ethicon believes Dr. Walmsley’s opinions are lacking, Ethicon may attack those opinions on cross-examination. Ethicon’s Motion on this point is **DENIED**.

Ethicon next argues that I should exclude Dr. Walmsley’s opinion that Ms. Lindberg’s mesh exposure in 2010 was caused by the physical properties of the TVT Secur because it is irrelevant and factually unsupported. However, after reviewing the record, I find that this opinion is relevant and factually supported. To the extent Ethicon believes Dr. Walmsley’s opinions are lacking, Ethicon may attack those opinions on cross-examination. Ethicon’s Motion on this point is **DENIED**.

Ethicon next argues that I should exclude Dr. Walmsley’s opinion that the way the TVT Secur was cut led to Ms. Lindberg’s mesh exposure because it is *ipse dixit*. However, after reviewing the record, I find that this opinion is relevant and factually supported. To the extent Ethicon believes Dr. Walmsley’s opinions are lacking, Ethicon may attack those opinions on cross-examination. Ethicon’s Motion on this

point is **DENIED**.

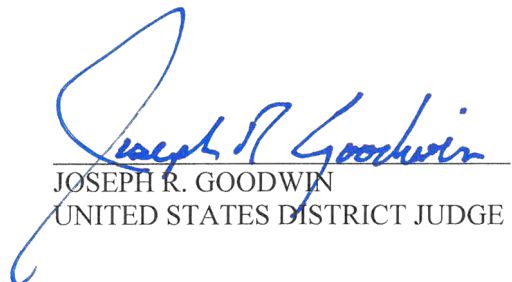
Finally, Ethicon argues that I should exclude Dr. Walmsley's testimony regarding Ms. Lindberg's implanting physician's state of mind. To the extent that testimony seeks to attribute a state of mind to the implanting surgeon, I agree with Ethicon. Experts may not testify as to what other individuals did or did not know. However, to the extent Ethicon seeks to exclude Dr. Walmsley's testimony about the adequacy of warnings and the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Ethicon's Motion is **GRANTED** to the extent they seek to exclude evidence regarding the implanting surgeon's state of mind, and any remaining issues are **RESERVED** for trial.

#### **IV. Conclusion**

The court **ORDERS** that the Motion to Exclude the Testimony of Konstantin Walmsley, M.D. [ECF No. 43] is **GRANTED in part, DENIED in part, and RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 16, 2017

  
JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE